

The opinion in support of the decision being entered today was *not* written for publication and is *not* binding precedent of the Board.

Paper No. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

MAILED

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PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

ENZO PAOLETTI and  
DENNIS PANICALI  
Junior Party<sup>1</sup>

v.

ENZO PAOLETTI and  
DENNIS PANICALI  
Junior Party<sup>2</sup>

v.

BERNARD MOSS, MICHAEL MACKETT  
and GEOFFREY L. SMITH  
Senior Party<sup>3</sup>

Interference No. 103,399

<sup>1</sup> Application 08/228,926, filed July 18, 1994. Accorded benefit of Serial Nos. 07/881,995, filed May 4, 1992, now abandoned; 07/537,882, filed June 14, 1990, now Patent No. 5,110,587, granted May 5, 1992; 07/090,209, filed August 27, 1987, now abandoned; 06/622,135, filed June 19, 1984, now Patent No. 4,722,848, granted February 2, 1988; 06/446,824, filed December 8, 1992, now Patent No. 4,603,112, granted August 5, 1986.

<sup>2</sup> Patent 4,603,112, granted July 29, 1986, based on Application 06/446,824, filed December 8, 1982.

<sup>3</sup> Application 07/987,546, filed December 7, 1992. Accorded benefit of 07/539,169, filed June 18, 1990; 07/072,455, filed July 13, 1987; 06/555,811, filed November 28, 1983; 06/445,892, filed December 1, 1982; and 06/445,451, filed November 30, 1982.

FINAL DECISION

Before Metz, Pate and Scheiner, Administrative Patent Judges.

Metz, Administrative Patent Judge.

The final hearing in this interference was requested by the junior party, Paoletti et al., to review the *sua sponte* decision of the administrative patent judge (APJ) as set forth in paper Number 124. Specifically, Paoletti et al. requested a final hearing under 37 C.F.R. § 1.640(e)(1)(i) (see Paper Number 126) to review the APJ's *sua sponte* determination of no interference-in-fact (Paper Numbers 61 and 124). Final hearing was set for March 27, 2002, at 1:00 P.M. See Paper Number 147. Both parties attended the final hearing represented by their respective legal counsel.

THE PROCEEDINGS BELOW

This interference was declared on June 8, 1994. The time for filing preliminary statements and preliminary motions was set to expire on September 8, 1994. The parties requested and were granted an extension of time for filing said statements and motions until March 11, 1995. Sometime in early spring of 1996, the examiner who forwarded the parties' involved application and patent for declaration of this proceeding informed the APJ

assigned to the interference that Paoletti et al. had filed another application (Serial Number 08/228,926, filed on July 18, 1994) which Paoletti et al. urged should be added to this proceeding (see Paper Numbers 17 and 22 of Serial Number 08/228,926). The examiner ultimately forwarded said application to the Board<sup>4</sup> accompanied with her explanation of why, although she agreed it should be added to this proceeding, she was no longer of the opinion that the parties' claims "interfered" in the sense of 35 U.S.C. § 135(a) and 37 C.F.R. §§ 1.601(j) and 1.601(n). The APJ agreed with the examiner and informed the parties of his intention to add Paoletti et al.'s application Serial Number 08/229,926 to Interference Number 103,399. See Paper Numbers 59 and 60, especially the examiner's statement under 37 C.F.R. § 1.609(b) attached to Paper Number 60.

In Paper Number 61, the APJ, pursuant to his discretionary authority under 37 C.F.R. § 1.610(e), moved, *sua sponte*, for judgment in favor of both parties under 37 C.F.R. § 1.633(b) on the grounds that there was no interference-in-fact. Specifically, the APJ first found that there was no literal language in any of Paoletti et al.'s claims designated as corresponding to the count which required, as did all the Moss et al. claims designated as corresponding to the count, a vaccinia promoter sequence adjacent

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<sup>4</sup> 37 C.F.R. §1.601(c).

to DNA foreign to the vaccinia virus and which exerted transcriptional control over said foreign DNA. Additionally, the APJ found that the examiner's initial rationale for concluding that the parties were claiming the "same patentable invention" in the sense of 37 C.F.R. § 1.601(n) was founded on her observation that:

based on the level of the **TK** gene product expressed for **vP22** produced from **pDP202 TK/E** she could only explain the phenomenon by concluding that Paoletti et al. had inherently recombinantly prepared a vaccinia virus wherein the foreign DNA sequence encoding a foreign polypeptide (herpes **TK**) was adjacent to a vaccinia virus promoter sequence which exerted transcriptional control over the foreign DNA sequence.

See pages 4-5 of Paper Number 61. The examiner, based on newly discovered evidence, now concluded that for whatever reason **vP22** expressed the **TK** gene at the level indicated it was not the result of having prepared a vaccinia virus wherein the foreign DNA sequence encoding a foreign polypeptide was adjacent to a vaccinia virus promoter sequence and which vaccinia virus promoter sequence exerted transcriptional control over the foreign DNA.

After reviewing the examiner's newly discovered evidence, and in light of all the evidence relied upon earlier, the APJ indicated to the parties that he agreed with the examiner's conclusion that the parties' claims designated as corresponding to the count did not interfere because they did not define the

"same patentable invention" in the sense of 37 C.F.R. §§ 1.601(j) and 1.601(n). In so-holding, the APJ specifically found that the examiner's original conclusion based on the level of the TK gene product expressed for vP22 could not be due to a vaccinia virus promoter sequence adjacent to the exogenous DNA foreign to vaccinia virus and which vaccinia virus promoter exerted transcriptional control over the exogenous, foreign DNA because it appeared that all Paoletti et al.'s constructs prepared from plasmid pDP202 TK (plasmids A through K):

including vP22, have substantial amounts of endogenous vaccinia coding sequence separating the foreign gene from the vaccinia promoter controlling its expression. (footnote omitted)

See, generally, page 5, beginning at the first full paragraph, through the paragraph bridging pages 8 and 9 and, specifically, page 8, second full paragraph, of Paper Number 61. Thus, the APJ concluded that vP22 did not inherently describe (35 U.S.C. §102) the constructs claimed by Moss et al. The APJ also concluded that based on his findings there would have been no motivation to insert a foreign gene in Paoletti et al.'s construct adjacent to a vaccinia virus promoter because Paoletti et al. obtained expression without inserting a foreign gene adjacent to a vaccinia virus promoter which exerts transcriptional control over the foreign gene. See page 9 of Paper Number 61. Thus, the APJ

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concluded vP22 would not have rendered obvious (35 U.S.C. §103) the constructs claimed by Moss et al.

The APJ authorized the parties to respond to the *sua sponte* holding as they would respond to a preliminary motion by filing an opposition or by simply filing a paper expressing their views on the issues raised. The APJ also advised the parties that a decision on the preliminary motions already filed and the opportunity to file new preliminary motions addressing the newly added Paoletti et al. application were deferred until the issues raised *sua sponte* were resolved.

The parties thereafter requested and were granted various extensions of time to file their responses to the *sua sponte* findings of the APJ. In Paper Number 119, the APJ responded to various papers filed by the parties. Additionally, the APJ clarified his previous order concerning the nature of the responses and explained that:

the parties were only authorized to set forth their views on the *sua sponte* finding or file responsive motions by analogy to responsive motions filed under 37 C.F.R. § 1.633(i).

The APJ acknowledged Moss et al.'s intention not to file any views with respect to the *sua sponte* findings and explained why the papers filed by Paoletti et al. were not responsive to the earlier order.

In reiterating his previous order the APJ explained to the parties the nature of the responses which would be considered to be responsive and gave Paoletti et al. until March 23, 2001, to file their response. The APJ also explained that:

[i]f after considering Paoletti et al.'s response, if any, the undersigned adheres to his *sua sponte* finding the undersigned will issue an order to show cause "against" both parties. The parties would then be afforded an opportunity to respond to the order to show cause in the manner provided by 37 C.F.R § 1.640(e). Assuming Paoletti et al. requested a final hearing it would then be appropriate to request a testimony period but only with respect to the issue of no interference-in-fact. The "final hearing" requested by Paoletti et al. would be limited to the consideration of whether the *sua sponte* determination under §1.633(b) had been properly decided. If the Board decided the finding was properly based on substantial evidence, then a judgment reflecting that determination would be issued and this proceeding would be terminated. If the Board determined that the undersigned improperly made his determination under §1.633(b) then this interference will proceed and the undersigned, after a discussion with the parties, will determine how to proceed with respect to the motions which the undersigned deferred to "final hearing" in this decision and in his decision finding *sua sponte* there was no interference-in-fact between the parties' claims.

See pages 7 and 8 of Paper Number 119.

On March 20, 2001, Paoletti et al. filed a paper styled as "**PAOLETTI ET AL.'S RESPONSE AND OPPOSITION TO APJ METZ' SUA SPONTE ORDER OF NO INTERFERENCE-IN-FACT**" (Paper Number 121). On March 22, 2001, Moss et al. filed a responsive paper to Paoletti et al.'s response of March 20, 2001 (Paper Number 122).

The major thrust of Paoletti et al.'s response as set forth in Paper Number 121 was founded on Paoletti et al.'s mistaken belief that in making his *sua sponte* findings the APJ had relied upon published sequence data for a different strain (the Copenhagen strain) of the vaccinia virus than the strain actually used by Paoletti et al. in construct **vP22** (the WR strain). See paragraphs 3, 4, 5 and 12, for example. Moreover, Paoletti et al. concluded that the vaccinia promoter in the strain used by them was "immediately proximal to the unique **Bam**HI site in the **Hind**III F fragment of the WR strain of vaccinia virus used by Paoletti et al. in constructs **vP7**, **vP8**, **vP9** and **vP10**." See paragraph 7 on page 3 of Paper Number 121. Additionally, Paoletti et al. concluded that the declaration of Dr. Marion Perkus attached as Exhibit A to their response (PR 10-35<sup>5</sup>) "confirms" that there is only a "13 nucleotide separation between the vaccinia promoter sequence and the DNA foreign to vaccinia virus in each of **vP2**, **vP4**, and **vP6** constructs" and only a "23 nucleotide separation between the vaccinia promoter sequence and foreign coding DNA in the **vP11** construct." See paragraph 13 of paper Number 121.

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<sup>5</sup> References to Paoletti et al.'s record will be designated as PR, followed by the record page number, and references to the Paoletti et al. exhibits will be designated PX, followed by the exhibit number.

The entirety of Paoletti et al.'s argument below that is consistent with the relief they request here, urging that we rescind the APJ's *sua sponte* holding, is set forth in the second full paragraph on page 6 of Paper Number 121. Specifically, Paoletti et al. argued that the Perkus declaration, along with the references submitted with their response "clearly demonstrates that the *sua sponte* holding is based on an incorrect understanding of the actual physical structure of the vaccinia virus used by Paoletti et al." In other words, Paoletti et al. maintained that the APJ's findings were made using the structure of the wrong strain (Copenhagen) of the vaccinia virus used by Paoletti et al. (WR) to make their constructs.

Moss et al.'s response to Paoletti et al.'s paper disputed, *inter alia*, the accuracy of Paoletti et al.'s material facts numbers 3 through 15, and also argued that certain constructs urged by Paoletti et al. as supporting the relief requested by them were constructs that did not "correspond to the count" and were therefore, irrelevant. See page 2 of Paper Number 122. Additionally, Moss et al. argued that various constructs relied on by Paoletti et al. included a herpes simplex virus thymidine kinase (HSV TK) promoter (a nonvaccinia promoter) that separated the gene to be expressed from the endogenous vaccinia promoter. See page 3 of Paper Number 122. Moss et al. also argued that for

constructs **vP7**, **vP8**, **vP9** and **vP10**, the endogenous vaccinia promoters would not be proximal to the foreign gene because of the "intervening non-vaccinia promoter." Finally, Moss et al. addressed the APJ's specific findings with respect to **vP22** and agreed with his determination that **vP22** had a "vast expanse of nucleotides that separated the endogenous vaccinia promoter from the HSV TK gene in **vP22**." Moss et al. observed that Paoletti et al.'s response did not contest the APJ's finding with respect to **vP22**. See page 5 of paper Number 122.

In his Order to Show Cause (Paper Number 124), the APJ concluded that he would adhere to his prior *sua sponte* determination of no interference-in-fact. The APJ set forth his analysis for why, assuming Paoletti et al.'s claims designated as corresponding to the count were "prior art" with respect to Moss et al.'s claims designated as corresponding to the count they would not have "anticipated" Moss et al.'s claims because "the subject matter of Moss et al.'s claims is not described by any claim of Paoletti et al. designated as corresponding to Count 1." See page 3 of Paper Number 124. The APJ reiterated the examiner's stated position that she had concluded intuitively from the level of the **TK** gene expression for **vP22** that the **HSV** **TK** exogenous DNA must have been adjacent to a vaccinia virus promoter sequence which exerted transcriptional control over the exogenous DNA

sequence. Therefore, the APJ concluded, it was the examiner's original position that Paoletti et al.'s claims designated as corresponding to the count inherently described, in the sense of §102, the subject matter of Moss et al.'s claims designated as corresponding to the count.

After pointing out that he had relied on Kotwal et al.'s published sequence for the WR strain for the **AvaI H** fragment of vaccinia virus in making his *sua sponte* finding and not the Copenhagen strain as Paoletti et al. had alleged, the APJ observed that most of his analysis:

was directed to Paoletti et al.'s "E" construct (pDP202 TK/E, Example XXV) which was Paoletti et al.'s construct which yielded the greatest level of expression and which also formed the basis of the examiner's initial determination that, for whatever reason expression was obtained, Paoletti et al. must have inherently made constructs in which the promoter was adjacent to and exerted transcriptional control over the DNA foreign to the vaccinia virus.

See the paragraph bridging pages 4-5 of paper Number 124. The APJ explained that his analysis of the "E" construct (vP22) was a reference to the **Hind III H** fragment shown in Figure 6A of Paoletti et al.'s involved patent and which is a restriction map of the WR strain of the vaccinia virus.

At page 5 of Paper Number 124 the APJ agreed with Moss et al. that Paoletti et al. had not:

challenged or adequately explained why the undersigned's determination of no interference-in-fact was erroneous with respect to either Paoletti et al. claims 40 and 49, both limited to vP22 constructs and with respect to claim 7, to the extent claim 7 recites vP22.

Recognizing that Paoletti et al.'s claim 7 recited a Markush group of constructs the APJ noted that Paoletti et al.'s response was limited to a discussion of constructs prepared using the Hind III F fragments and that the only constructs discussed by Paoletti et al. using said fragments were vP7, vP8, vP9 and vP10 in claim 7. See the first full paragraph on page 6 of Paper Number 124.

The APJ then observed that for vP7 and vP8 there was "no coding sequence under control of the vaccinia virus promoter." For constructs vP9 and vP10, the APJ determined that there were substantial amounts of the sequence from pBR322 between the vaccinia promoter and the coding sequence and that he could not, therefore, determine the basis for Paoletti et al.'s conclusion in paragraph 7 of their response that the vaccinia promoter was "immediately proximal" to the BamHI site. The APJ concluded that because vP9 and vP10 had significantly higher numbers of base pairs between the vaccinia promoter and the foreign DNA, neither construct could be said to inherently meet the requirement of all Moss et al.'s claims designated as corresponding to the count

that the vaccinia promoter is both adjacent to and exerts transcriptional control over said foreign DNA.

The APJ also discussed constructs vP2, vP4, vP6 and vP11 which are recited as part of the Markush group in claim 7. The APJ agreed with Moss et al. that because each of these constructs included a HSV TK promoter between the exogenous DNA and the vaccinia virus promoter the constructs would, necessarily, separate the coding region from any endogenous vaccinia virus promoters.

The APJ concluded that the claims of the parties were directed to "separate patentable inventions in the sense of 37 C.F.R. § 1.601(n)" and that there was no interference-in-fact between the parties' claims designated as corresponding to the count. The APJ then explained the nature of the judgment he would issue and gave the parties 20 (twenty) days in which to respond to the order to show cause pursuant to 37 C.F.R. § 1.640(e). Finally, the APJ advised the parties that any "final hearing", if requested, would be limited to consideration of the propriety of the *sua sponte* finding of no interference-in-fact.

On October 18, 2001, the APJ issued an order granting Paoletti et al.'s request for final hearing to review the finding of no interference-in-fact. In granting the motion for final hearing, the APJ advised the parties that:

Pursuant to 37 C.F.R. § 1.655(a) (1999), the undersigned's decision is reviewed *de novo*, without deference to the findings and decision below but the review is based on the record before the undersigned when the decision was reached. See the notice of the interim final rule in 64 F.R. 12900, which interim final rule became effective on March 16, 1999. The parties are reminded that although there is no longer a presumption of correctness for all interlocutory decisions set forth in 37 C.F.R. § 1.655(a), the purpose of the final hearing is for reviewing the decision of the undersigned, based on the record then before him, and the burden of showing the order should be modified is on party attacking the order. 37 C.F.R. § 1.655(a), third sentence. Accordingly, Paoletti et al., the party seeking to modify the undersigned's interlocutory finding of no interference-in-fact, bears the burden of showing that the order should be modified.

The APJ also granted Paoletti et al.'s motion for a limited testimony period "but only to the extent the parties shall be given an opportunity to present the evidence of record on which they intend to rely in seeking review of the undersigned's *sua sponte* finding of no interference-in-fact."

**THE MOTION TO SUPPRESS**

After Paoletti et al. served their brief on Moss et al., Moss et al. filed a motion to suppress pursuant to 37 C.F.R. §§ 1.635 and 1.656(h) (Paper Number 136). Therein, Moss et al. seek to suppress Paoletti et al. Exhibit A which is attached to Paoletti et al.'s brief.

In the order granting Paoletti et al.'s motion for a limited testimony period, the APJ advised the parties in no uncertain terms that:

evidence relied on by them in connection with the undersigned's *sua sponte* finding from which review is now sought will be given no consideration at final hearing unless the evidence is introduced in accordance with the rules during the time period set forth below. See 37 C.F.R. § 1.671(e).

See Paper Number 131, page 6. The parties were given 1 (one) week in which to introduce all the evidence on which they sought to rely.

According to Moss et al.'s motion, Exhibit A attached to Paoletti et al.'s brief was presented for the first time with their brief and was not introduced in accordance with the APJ's order. According to Paoletti et al.'s opposition to the motion to suppress, Exhibit A is merely "an aid to the Board in understanding the structure of the vP11 virus." Paoletti et al. represent that the evidence underlying the exhibit may be found in various evidence all of which is of record.

According to the APJ's order and 37 C.F.R. § 1.671(e), evidence not properly introduced in accordance with his order and the rules would be given no consideration at final hearing. Accordingly, because Paoletti et al. does not allege that Exhibit A was ever introduced into evidence in the manner provided by the rules or in the APJ's order and because Paoletti et al. rely on Exhibit A as evidence to prove their case in their brief (see, for example, page 8 of the brief), Moss et al.'s motion to

suppress Exhibit A is GRANTED. We shall not, therefore, consider Exhibit A for any purpose in reviewing the issues presented for final hearing by the parties.

THE APJ'S FINDING OF NO INTERFERENCE-IN-FACT

As the party requesting final hearing to review the APJ's interlocutory order finding no interference-in-fact, Paoletti et al. bear the burden of proving the APJ's interlocutory order should be modified. See 37 C.F.R. § 1.655(a), third sentence.

Before we begin our analysis of the parties' respective positions, we note that the requirements for the parties' briefs are set forth in 37 C.F.R. §§ 1.656(b)(1) through 1.656(b)(8). 37 C.F.R. § 1.656(b)(6) specifically requires the brief to contain an argument which:

shall contain the contentions of the party with respect to the issues it is raising for consideration at final hearing, and the reasons therefor, with citations to the cases, statutes, or other authorities, and parts of the record relied on. [emphasis added]

Mere presentation of facts, evidence and conclusions without specific citations in the argument to the legal theory on which a party relies and the cases, statutes, parts of the record or other authorities which support a party's position on an issue does not comply with rule or aid us in our resolution of the issues.

We have, of course, reviewed the entire record in this interference, including all of the declaration testimony and exhibits submitted by the parties. Nonetheless, we shall not relieve the parties of their burden under the rules and speculate as to what is the basis for the conclusions of fact and law made by them in their briefs where no adequate specific reference to the record or citation of authority is proffered by them. Neither shall we search through the record to find facts which might support the positions taken by them in their briefs. Rather, conclusions of fact and law made without appropriate citation to the record or citation of authority will be taken as mere attorney argument. Compare Ex parte McCullough, 7 USPQ2d 1889 (BPAI 1988); Ex parte Myer, 6 USPQ2d 1966 (BPAI 1988); In re Mehta, 347 F.2d 859, 146 USPQ 284 (CCPA 1965).

It is apparent from: the examiner's statements under 37 C.F.R. § 1.609(b); the APJ's order wherein he first made his *sua sponte* holding; and, the order to show cause, that this interference was declared based on the examiner's initial determination that the parties were claiming the "same patentable invention" founded on her analysis of the vP22 construct from Paoletti et al.'s involved patent. Specifically, the examiner expressly relied on Example XXV in Paoletti et al.'s involved patent and the level of expression for **HSV TK** obtained therefrom.

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See the examiner's statements under 37 C.F.R. § 1.609(b) filed as part of the original declaration papers; Paper Number 60; page 4 of Paper Number 61; and, the paragraph bridging pages 3 and 4 of Paper Number 124.

In pages 5 through 9 of Paper Number 61, the APJ analyzed the examiner's newly found evidence and determined that in construct vP22 the location of the foreign gene was more than 800 bases downstream of the initiation codon and not near the presumptive promoter. In the paragraph bridging pages 5 and 6 of paper Number 124, the APJ observed that Paoletti et al.'s response to Paper Number 61 had failed to challenge or explain why the APJ's determination that vP22 was not directed to the "same patentable invention" as any of Moss et al.'s claims designated as corresponding to the count was erroneous. Nothing in Paoletti et al.'s brief or reply brief challenges or refutes the APJ's findings below with respect to construct vP22.

We find that the APJ's findings below with respect to construct vP22 were supported by substantial evidence. Thus, the APJ satisfied his burden of rebutting the presumption which adheres upon declaration of an interference that claims originally designated as corresponding to the count are directed to the "same patentable invention." Accordingly, we agree with the APJ's conclusion that Paoletti et al.'s involved application

claims 40 and 49 and which are directed to construct **vp22** are not directed to the "same patentable invention" as any of Moss et al.'s claims designated as corresponding to the count. We also agree that the APJ's conclusion that claim 7 of Paoletti et al.'s involved patent, to the extent claim 7 recites **vp22** as one member of a Markush group of constructs, is not directed to the "same patentable invention" as any claim of Moss et al. which is designated as corresponding to the count.

We also find that although claim 7 recites a Markush group of constructs including **vp22**, the examiner considered **vp22** to be the only member of the Markush group which "interfered" with the claims of Moss et al. This finding is supported by: the examiner's statements under §1.609(b) which are entirely limited to **vp22**; the APJ's initial *sua sponte* finding as set forth in Paper Number 61; and, the APJ's reasoning for maintaining his finding of no interference-in-fact as set forth in the order to show cause (Paper Number 124). Additionally, certain members of Paoletti et al.'s Markush group claimed in claim 7 (pDP137; **vp2**, **vp4**, **vp6** and **vp9**) are also specifically claimed by Paoletti et al. in their involved application (claims 39, 48 and 50, respectively) but those application claims have been designated as not corresponding to the count. As claims designated as not corresponding to the count, these claims are presumed to be

directed to a "separate patentable invention"<sup>6</sup> from every claim designated as corresponding to the count. Thus, claim 7 of Paoletti et al.'s involved patent was designated as corresponding to the count by the examiner, not because every member of the Markush group was believed to be directed to the "same patentable invention," but because claim 7 included construct vP22 which, when recombinantly combined with VTK-79L, induced a significantly higher level of expression than any other construct recited in Paoletti et al.'s disclosure or the Markush group of claim 7.

As recognized by the APJ in Paper Number 124, almost the entirety of Paoletti et al.'s response to the initial *sua sponte* finding was directed, not to vP22, but to vP7, vP8, vP9 and vP10 (see the first full paragraph on page 6 of Paper Number 124). For reasons which Paoletti et al. have not challenged or refuted here, the APJ concluded that for each of the constructs vP7, vP8, vP9 and vP10 there was either no coding sequence under the control of the vaccinia virus (vP7 and vP8) or the constructs had substantial amounts of DNA separating the sequence encoding a polypeptide from the vaccinia promoter controlling its expression (vP9 and vP10). We reiterate, nothing in Paoletti et al.'s brief addresses let alone challenges these determinations made by the

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<sup>6</sup> 37 C.F.R. §1.601(n), second sentence.

APJ. Moreover, as noted above, claim 50 of Paoletti et al.'s involved application, which is a claim designated as not corresponding to the count, is directed to **vP9** which raises a rebuttable presumption that **vP9** is not directed to the "same patentable invention" as **vP22**, the invention claimed in claims 40 and 49 of Paoletti et al.'s involved application.

In paragraph 7 on page 5 of their main brief Paoletti et al. quote, out of context, a portion of the APJ's discussion of the constructs **vP7**, **vP8**, **vP9** and **vP10** from page 7 of the order to show cause. The quoted section, in its entirety, reads as follows (underlining shows portion omitted by Paoletti et al. in their brief):

Paoletti et al. correctly concludes in paragraph 12 on page 4 of Paper Number 121 that constructs made by inserting exogenous DNA in the **BAM HI** site of the **Hind III F** fragment do not have substantial amounts of endogenous vaccinia coding sequence separating the foreign gene from the vaccinia promoter controlling its expression. Nevertheless, there is still a substantial amount of DNA separating the sequence encoding a polypeptide from the vaccinia promoter controlling its expression in each of Paoletti et al.'s vP9 and vP10 constructs. Thus, the basis for Paoletti et al.'s conclusion in paragraph 7 on page 3 of their response that the vaccinia promoter is "immediately proximal" to the **BamHI** site cannot be determined.

In paragraph 8 on page 5 of their main brief, after the out-of-context quote, Paoletti et al. leap to the APJ's discussion on page 8 of the order to show cause where the APJ discusses not the

vP7, vP8, vP9 and vP10 constructs but constructs vP2, vP4, vP6 and vP11.

In their response to the APJ's *sua sponte* findings, Paoletti et al. argued apart from constructs vP7, vP8, vP9 and vP10 that in constructs vP2, vP4, vP6 and vP11 the promoter used by Paoletti et al. was "immediately proximal to the unique BamHI site in the HindIII F fragment used to insert exogenous DNA into the recombinant vaccinia virus of Paoletti et al." The basis for these conclusions was alleged to be the declaration of Dr. Perkus submitted with their response (PX 20). The APJ observed that for constructs vP2, vP4, vP6 and vP11 there was an HSV TK promoter between the foreign DNA and the vaccinia virus promoter. Thus, the APJ reasoned, those constructs included non-vaccinia promoters which separated the coding region from the vaccinia virus promoters and the constructs were, therefore, not the "same patentable invention" as claimed by Moss et al. The APJ further responded by observing that Dr. Perkus' declaration did not perform a claim-by-claim analysis in which Moss et al.'s claims were considered as "prior art" with respect to Paoletti et al.'s claims. Thus, the APJ could not accept Dr. Perkus' various unsupported conclusions.

We have carefully reviewed the APJ's findings below in the context in which the findings were made. With respect to the

constructs **vP2**, **vP4** and **vP6**, we find the APJ properly found, based on substantial evidence, that these constructs included an **HSV TK** promoter between the exogenous DNA and the vaccinia virus promoter, a fact not challenged or refuted here. Thus, claim 7, to the extent it includes these constructs, cannot be directed to the "same patentable invention" as any of Moss et al.'s claims designated as corresponding to the count because these constructs did not include a vaccinia virus promoter sequence adjacent to DNA foreign to the vaccinia virus and which promoter sequence exerted transcriptional control over said foreign DNA.

Paoletti et al. now argue that the APJ erred in Paper Number 124 in his determination of the structure of construct **vP11**. While Paoletti et al. argued in the most generic sense at page 6 of their response to the *sua sponte* finding that the promoter in **vP11** was "immediately proximal" to the **BamHI** site used to insert exogenous DNA in the vaccinia virus used by Paoletti et al., the Perkus declaration on which Paoletti et al. relied did not prove what was the actual structure of **vP11**. Although it is also clear from the examiner's statements under 37 C.F.R. § 1.609(b) that the basis for her original conclusion that the parties' claims interfered did not include any discussion of **vP11**, we agree with Paoletti et al. that the APJ erred in his determination that **vP11**

included an intervening HSV TK promoter between the exogenous DNA and the vaccinia virus promoter.

As is clearly shown in Paoletti et al.'s involved patent at column 5, lines 9 through 15, vP11 was prepared using the DNA sequence coding for the surface antigen of hepatitis B virus not the herpes simplex virus. However, Paoletti et al.'s argument with respect to vP11 in their response to the APJ's *sua sponte* finding was a discussion in the context of Paoletti et al.'s erroneous argument that the APJ had relied on the wrong vaccinia virus strain in making his *sua sponte* findings. Additionally, it cannot be determined from: Paoletti et al.'s response to the *sua sponte* findings; Paoletti et al.'s brief; or, from Dr. Perkus' declaration (PX 20) on which Paoletti et al. rely to prove the structure of vP11, what forms the basis for Paoletti et al.'s arguments or Dr. Perkus' opinions and conclusions.

Paoletti et al.'s oblique generic references in their brief to Dr. Perkus' declaration and to Dr. Perkus' analysis in paragraphs 16 through 18 of Paoletti et al.'s "statement of the facts" from their brief lacks adequate specificity. Exactly how did Dr. Perkus "confirm" that only 23 nucleotides separated the vaccinia promoter sequence and the coding DNA in vP11? What was

the exact basis for Dr. Perkus' "expert opinion" that **vP2**, **vP4**, **vP6** and **vP11**:

describe and suggest recombinant vaccinia virus wherein the promoter sequence is "adjacent to" the foreign DNA and which promoter sequence exerts transcriptional control over the foreign DNA.

Where is Dr. Perkus' analysis of the "constructs of the Moss applications" specifically set forth and where are the constructs of **vP2**, **vP4**, **vP6** and **vP11** compared with Moss et al.'s claims?

Where is the structure of **vP11** "described in the '112 patent?"

Accepting for the sake of argument that Dr. Perkus is an expert<sup>7</sup>, even the opinion of an expert must find a foundation in the evidence. Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 1025, 226 USPQ 881, 887 (Fed. Cir. 1985); In re Grunwell, 609 F.2d 486, 491, 203 USPQ 1055, 1059 (CCPA 1979).

Absent specific references to the underlying basis for Dr. Perkus' opinions and conclusions, we consider the same to have the same weight as attorney argument. Paoletti et al.'s oblique generic references are considered to be an invitation to this Board to review the record and find evidence which supports the position taken by Paoletti et al. in their brief. We decline to accept Paoletti et al.'s invitation.

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<sup>7</sup> See Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S.Ct. 2786 (1993) for a complete discussion of the standard for admitting expert scientific testimony.

Paoletti et al. have simply failed to direct us in their brief to the specific evidence in the record which supports their arguments concerning the structure of vP11. Accordingly, in light of Paoletti et al.'s failure to analyze any of Moss et al.'s claims designated as corresponding to the count and in light of Paoletti et al.'s failure to prove by preponderance of the evidence that the structure for vP11 meets the limitations for any of Moss et al.'s claims designated as corresponding to the count, we find that Paoletti et al. have failed to carry their burden of persuasion.

At page 9 of their main brief, Paoletti et al. recognize that the question of whether or not the claims of two or more parties may be said to interfere is determined by a comparison of the parties' claims designated as corresponding to the count and determining whether or not said claims define the "same patentable invention." As correctly noted by Paoletti et al., an interference-in-fact exists when at least one claim of a party designated as corresponding to the count and at least one claim of an opponent designated as corresponding to the count define the "same patentable invention." See 37 C.F.R. 1.601(j). The definition of "same patentable invention" is set forth in 37 C.F.R. § 1.601(n).

Paoletti et al. expressly recognize that the issue of whether an interference-in-fact exists requires the analysis and comparison of the parties' claims. Nevertheless, except for Paoletti et al.'s characterization of Moss et al.'s claims as "genus claims" at page 9 of their brief and an extremely brief discussion of the term "adjacent" in Moss et al.'s claims at page 10 of their main brief made without regard to any claim of Moss et al. designated as corresponding to the count, there is no analysis of any of Moss et al.'s claims designated as corresponding to the count in either Paoletti et al.'s main brief or reply brief.

Moss et al.'s claim 33 is exemplary of Moss et al.'s claims designated as corresponding to the count. The claim is directed to a "plasmid" comprising a first segment of a first DNA sequence encoding a polypeptide foreign to vaccinia virus and a vaccinia virus promoter sequence wherein the vaccinia virus promoter sequence is not only "adjacent to" the DNA encoding a polypeptide foreign to vaccinia virus but also exerts transcriptional control over said first DNA sequence and, flanking said first segment, DNA from a nonessential region of a vaccinia genome.

Nowhere in Paoletti et al.'s brief is there a "reading" of the structure for vP11 on, for example, Moss et al.'s claim 33. Thus, we are unable to ascertain whether or not in vP11 there is

a vaccinia virus promoter adjacent to the hepatitis virus surface antigen sequence ("a first DNA sequence encoding a polypeptide foreign to vaccinia virus") and which vaccinia virus promoter exerts transcriptional control over the hepatitis virus surface antigen sequence and whether or not there is also, flanking the vaccinia promoter/foreign gene segment, DNA from a nonessential region of the vaccinia genome. Notwithstanding Paoletti et al.'s reliance on the disclosure in the specification of their involved patent for the structure of **vP11** (see page 9 of the main brief), neither the actual structure for **vP11** nor whether or not the "**HBVsAg** coding DNA within 23 nucleotides of the endogenous vaccinia virus promoter" is, in fact, within the number of nucleotides recited can be determined from the disclosure of their involved patent.

We have not overlooked Paoletti et al.'s generic reference to the Boyle et al. and Coupar et al. references as being "of record in this interference" (see page 4 of the reply brief) but the mere fact that the references are of record is not adequate. It was Paoletti et al.'s burden to cite to specific portions of the evidence of record, including Boyle et al. and Coupar et al., which supported the contentions of Paoletti et al. with respect to the issues raised by them. It is not our duty to search for

evidence in the record, including Boyle et al. and Coupar et al., which may support Paoletti et al.'s argued position.

In their reply brief at page 3 and in their oral argument at final hearing, Paoletti et al. have somehow suggested that the APJ's order, which limited the issue to be briefed at final hearing to whether or not the parties' claims designated as corresponding to the count interfered, in some way precluded Paoletti et al. from analyzing the scope and content of Moss et al.'s claims designated as corresponding to the count. At page 3 of their reply brief, Paoletti et al. have reproduced in part the APJ's order limiting the issue at final hearing to the question of whether there exists an interference-in-fact. We cannot fathom from that part of the order reproduced how Paoletti et al. could argue that the APJ precluded the parties from addressing the meaning of the terms in the parties' respective claims. An interference-in-fact is defined in the rules in terms of the parties' claims. The test for determining whether the parties' claims define the "same patentable invention" requires a patentability test which requires a comparison of the parties' claims. Indeed, we cannot understand how Paoletti et al. could meet their burden of proof here or even perform the test for determining whether the parties claim the "same patentable

"invention" without analyzing both their claim terminology and their opponents' claim terminology.

It does not serve Paoletti et al.'s position to argue as they have in their brief that the meaning of certain terms in Moss et al.'s claims designated as corresponding to the count "is of record and the subject of Preliminary Motions." See page 3 of the reply brief. As we have stated above, the rules require a party's brief to set forth in the argument section the contentions of the parties with respect to the issues it is raising and include citations to the record, cases, statutes and other authorities on which it relies to support the contentions made in the brief. This Paoletti et al. have not done.

At page 2 of their reply brief, Paoletti et al. argue that it was not necessary for them to prove that the APJ's analysis of the vP22 construct and, thus, his finding of no interference-in-fact was wrong in order to go forward in this proceeding. Moss et al. argue that vP11 is not in issue here because Paoletti et al. failed to move to designate any claims which recite vP11 as claims corresponding to the count. Paoletti et al. are correct on this matter. But, as inferentially suggested by Paoletti et al.'s argument, it remained Paoletti et al.'s burden to prove that at least one claim of their involved patent or application designated as corresponding to the count defined the "same

patentable invention" as at least one claim of Moss et al.'s application designated as corresponding to the count. For the reasons expressed above, this Paoletti et al.' have failed to do.

We reiterate that for Paoletti et al.'s involved application claims 40 and 49, we find that the APJ correctly found based on substantial evidence that vP22, the construct to which claims 40 and 49 are limited, is not directed to the "same patentable invention" as any claim of Moss et al. designated as corresponding to the count. Paoletti et al. have not challenged or refuted this finding. To the extent Paoletti et al.'s patent claim 7 includes vP22, the APJ's finding of no interference-in-fact with that claim and any claim of Moss et al.' designated as corresponding to the count was also correct.

As the party urging that claim 7 included a construct, vP11, that was directed to the "same patentable invention" as the invention claimed by Moss et al. in at least one of Moss et al.'s claims designated as corresponding to the count, Paoletti et al. bore the burden of proving: (1) what the actual structure for the construct vP11 is; and, (2) that vP11 from claim 7 would have either anticipated, in the sense of 35 U.S.C. § 102, or would have rendered obvious, in the sense of 35 U.S.C. § 103, at least one of Moss et al.'s claims designated as corresponding to the

count, assuming vP11 was "prior art" to Moss et al. Paoletti et al. have failed to prove either.

At page 9 of their main brief, Paoletti et al. cite Winter v. Takashi, 53 USPQ2d 1234 (BPAI 1999) for the proposition that determination of whether there is an interference-in-fact pursuant to 37 C.F.R. § 1.601(n) involves a two-way patentability analysis. We need not address whether or not this decision from the "trial section" is an accurate statement of the law<sup>8</sup> because Paoletti et al. have failed to perform the two-way test they state is required by Winter before reaching a finding of an interference-in-fact. According to Paoletti et al.'s terse analysis and based on Paoletti et al.'s conclusory statements of facts, Paoletti et al. urge that construct vP11 is a species within "Moss et al.'s claimed genus." Paoletti et al. conclude, based on well-known case law, that a species within a genus anticipates (35 U.S.C. § 102) the genus. See page 9 of Paoletti et al.'s main brief. Glaring by its absence in Paoletti et al.'s brief is the second part of the two-way test including any analysis explaining on what basis Moss et al.'s "claimed genus" would have rendered Paoletti et al.'s specific construct, vP11,

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<sup>8</sup> The decision is specifically noted therein as binding precedent on the trial section. Thus, we are not bound by this opinion.

unpatentable under either 35 U.S.C. § 102 or 103. Accordingly, and assuming, *arguendo*, the truthfulness of the facts alleged by Paoletti et al., Paoletti et al. have failed to prove there is an interference-in-fact between the parties using the very test for an interference-in-fact from the case on which they rely in their brief.

Finally, we observe that the APJ found that the examiner's originally stated rationale for concluding there was an interference-in-fact was based on the level of expression for the construct **vP22** in Paoletti et al.'s involved patent. We also observe that there is no expression for the **vP11** construct in Paoletti et al.'s involved patent. Accordingly, when this interference was declared, there was no basis for Paoletti et al.'s current argument that the vaccinia promoter exerted transcriptional control over the foreign DNA because there was no evidence of expression of record for **vP11** when this interference was initially declared. In their argument, Paoletti et al. now urge that "the **vP11** construct expresses the **HBVsAg** protein encoded by the foreign DNA inserted at the **BamHI** site in the **Hind III F** fragment of vaccinia virus." The basis for this apparent conclusion is the table after Example XXXII of U.S. Patent No. 4,722,848 (PX13) which is set forth in Paoletti et al.'s statement of facts but not referenced in their argument (see

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paragraph 13 on page 6 of the main brief and the first full paragraph on page 10 of their main brief).

We have carefully reviewed the table and Example XXXII of Paoletti et al.'s Patent Number 4,722,848 and cannot determine therefrom exactly what is the level of expression or whether the level of expression is so high, as with vP22, as to suggest that the construct inherently must satisfy the requirements of Moss et al.'s claims for both adjacency and exertion of control over expression. Suffice it to say that the results for the table and Example XXXII are not self-explanatory and Paoletti et al. have chosen not to explain the relevance of said table or example in their brief.

We have found that the APJ's interlocutory finding of no interference-in-fact between the parties' claims designated as corresponding to the count was correct and based on substantial evidence. Our finding of no interference-in-fact is dispositive of this interference because, absent the presence of interfering subject matter, there is no longer any apparent jurisdictional basis under 35 U.S.C. § 135(a) for proceeding further under the rules promulgated by the Director for conducting interferences. Accordingly it is now appropriate to issue judgment in this proceeding.

We also note that Paoletti et al. have filed various preliminary motions which were deferred until the issue of an interference-in-fact was resolved. These deferred motions are now **DISMISSED**. Nevertheless, to the extent these motions raise issues concerning the patentability of Moss et al.'s claims designated as corresponding to the count, Moss et al. has a duty under 37 C.F.R. § 1.56 to bring to the examiner's attention the issues raised by Paoletti et al. in their preliminary motions when their application is returned to the examiner for further examination not inconsistent with this decision.

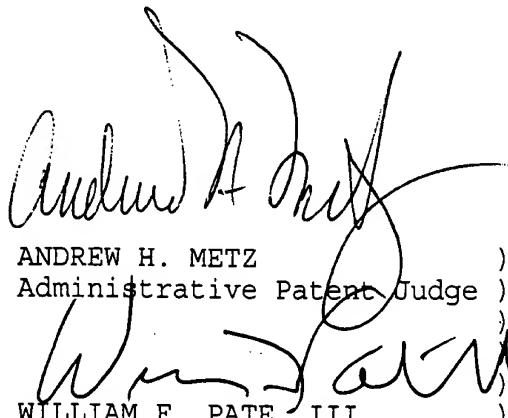
JUDGMENT

Accordingly, pursuant to 37 C.F.R. 1.658(a):

On this record, Enzo Paoletti and Dennis Panicali, the junior party are entitled to a patent containing claims 40 and 49 designated as corresponding to the count of their involved application Serial Number 08/228,926; and, on this record, Enzo Paoletti and Dennis Panicali, the junior party, are entitled to claim 7 designated as corresponding to the count of their involved patent, U.S. Patent Number 4,603,112.

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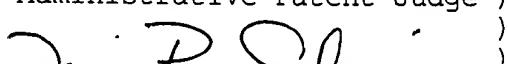
On this record, Bernard Moss, Michael Mackett and Geoffrey L. Smith, the senior party, are entitled to a patent containing claims 33, 36, 37, 39, 41 through 44, 47, 48, 50 and 52 through 57 designated as corresponding to the count of their involved application, Serial Number 07/987,546.



ANDREW H. METZ )  
Administrative Patent Judge )



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